P11073-10419

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Type of Project: Modify Existing Approved PAR
PAR Request Date: 21-Jan-2013
PAR Approval Date: 06-Mar-2013
PAR Expiration Date: 31-Dec-2014
Status: Modification to a Previously Approved PAR
Root PAR: P11073-10419 **Approved on:** 10-Dec-2008

1.1 Project Number: P11073-10419
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for Health informatics - Personal health device communication - Device specialization - Insulin pump

3.1 Working Group: Personal_Health_Device (EMB/11073/PHD)
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3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/IEEE 11073TM Standards Committee (EMB/11073)
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4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 12/2009
4.3 Projected Completion Date for Submittal to RevCom: 10/2014

5.1 Approximate number of people expected to be actively involved in the development of this project: 15

5.2 Scope: The scope of this standard is to establish a normative definition of communication between personal telehealth insulin pump devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of functionality of personal telehealth insulin pump devices.

In the context of personal health devices, an insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII) therapy.

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Changes in scope: The scope of this standard is to establish a normative definition of communication between personal telehealth insulin pump devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of functionality of personal telehealth insulin pump devices. In the context of personal health devices, an insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII) therapy. This standard provides the data modeling ~~and its transport shim layer~~ according to the ISO/IEEE11073-20601 standard, and does not specify the measurement method.

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5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

5.5 Need for the Project: The complexity of personal telehealth devices differs sufficiently from other ISO/IEEE 11073 point of care medical devices to require derivative standards so this standard is tailored to address the particular needs of the personal telehealth market. Implementers of this standard will have a clear definition of what is required to implement an insulin pump device. For end users, this standard addresses a market need to provide interoperability among personal telehealth devices and managers that interact with the collected information.

5.6 Stakeholders for the Standard: People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies (e.g. food and drug administration), telemedicine consultants and businesses.

Intellectual Property
6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No
6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

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7.1 Are there other standards or projects with a similar scope?: No
7.2 Joint Development
Is it the intent to develop this document jointly with another organization?: No

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8.1 Additional Explanatory Notes (Item Number and Explanation): 5.2: We take out the phrase 'and its transport shim layer' because this standard has nothing to do with the transport shim layer. It is the IEEE Std 11073-20601 which handles the transport shim layer. The proposed change is consistent with the PARs of other 11073-104zz projects.
IEEE Std 11073-20601:2008 Health informatics-Personal health device communication
Part 20601: Application profile-Optimized Exchange Protocol

IEEE Std 11073-20601a:2010 Health informatics-Personal health device communication
Part 20601: Application profile-Optimized Exchange Protocol, Amendment 1